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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SHIRLEY LINEBERRY, Plaintiff, v. PROCTER & GAMBLE PHARMACEUTICALS, INC. and AVENTIS PHARMACEUTICALS, INC., Defendants.	CIVIL ACTION NO. 1:07-CV-8831-PKC **ANSWER**

Procter & Gamble Pharmaceuticals, Inc. ("P&G") and sanofi-aventis U.S. L.L.C. ("sanofi-aventis"), successor in interest to Aventis Pharmaceuticals, Inc., answer Plaintiff Shirley Lineberry's ("Plaintiff") Original Complaint ("Complaint") as follows:

In response to the Plaintiff's first unnumbered paragraph, Defendant P&G admits that it is an Ohio corporation with its principal place of business in Cincinnati, Ohio. Defendant sanofi-

aventis, successor in interest to Aventis Pharmaceuticals, Inc., admits that it is a Delaware corporation with its principal place of business in New Jersey. P&G and sanofi-aventis admit that this is a civil action for alleged damages suffered by Plaintiff. However, P&G and sanofi-aventis deny that Plaintiff has suffered any damages as a result of her allegedly being prescribed and her alleged ingestion of the drug Actonel. To the extent this paragraph contains any additional allegations, P&G and sanofi-aventis deny any such allegations.

I. INTRODUCTION

1. In answer to paragraph 1 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. With regard to whether Plaintiff was prescribed and ingested Actonel, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and, therefore, deny the allegations. P&G and sanofi-aventis deny any remaining allegations.

II. PARTIES

A. PLAINTIFF

2. In answer to paragraph 2 of the Complaint, P&G and sanofi-aventis expressly deny any implication that Actonel is associated in any way with the injury alleged by Plaintiff. As to the remaining allegations, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and, therefore, deny the allegations.

B. DEFENDANTS

3. In answer to paragraph 3 of the Complaint, Defendant P&G admits that it is an Ohio corporation with its principal place of business in Ohio.

4. In answer to paragraph 4 of the Complaint, Defendant sanofi-aventis admits that sanofi-aventis U.S. L.L.C. is a Delaware corporation with its principal place of business in New Jersey.

5. In answer to paragraph 5 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. Defendant P&G denies that it conducts business in the State of North Carolina. Defendant sanofi-aventis admits that it conducts business in the State of North Carolina.

III. JURISDICTION AND VENUE

6. In answer to paragraph 6 of the Complaint, P&G and sanofi-aventis admit that jurisdiction is proper in federal court. P&G and sanofi-aventis further admit that Plaintiff and P&G and sanofi-aventis are citizens of different states. Although P&G and sanofi-aventis deny that Plaintiff is entitled to any damages whatsoever, P&G and sanofi-aventis admit that upon information and belief, the amount in controversy appears to be greater than $75,000.

IV. FACTUAL BACKGROUND

7. In answer to paragraph 7 of the Complaint, P&G and sanofi-aventis admit that Actonel is a brand name of risedronate sodium, that it is a prescription drug that is taken orally, and that Actonel was approved by the United States Food & Drug Administration ("FDA") for prevention and treatment of osteoporosis. P&G and sanofi-aventis deny any remaining allegations.

8. In answer to paragraph 8 of the Complaint, P&G and sanofi-aventis deny the allegations as stated. Because Plaintiff has failed to specifically identify the published case reports or medical literature referred to in paragraph 8, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and, therefore, deny the allegations.

9. In answer to paragraph 9 of the Complaint, P&G and sanofi-aventis admit that the FDA prepared a post-marketing review memorandum regarding bisphosphonates on August 25, 2004, which speaks for itself. P&G and sanofi-aventis deny the remaining allegations as stated. By way of further answer, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

10. In answer to paragraph 10 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

11. In answer to paragraph 11 of the Complaint, P&G and sanofi-aventis state that they had a duty to comply with all applicable law, which they did. By way of further answer, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge. P&G and sanofi-aventis deny any remaining allegations.

12. In answer to paragraph 12 of the Complaint, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and, therefore, deny the allegations.

13. In answer to paragraph 13 of the Complaint, P&G and sanofi-aventis expressly deny any implication that Actonel is associated in any way with the injury alleged by Plaintiff. As to the remaining allegations, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and, therefore, deny the allegations.

14. In answer to paragraph 14 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

COUNT I
STRICT LIABILITY

15. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 14 above.

16. In answer to paragraph 16 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. Defendant P&G denies that it conducts business in the State of North Carolina. Defendant sanofi-aventis admits that it conducts business in the state of North Carolina. Except as admitted, P&G and sanofi-aventis deny the allegations.

17. In answer to paragraph 17 of the Complaint, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted and, therefore, deny the allegations.

18. In answer to paragraph 18 of the Complaint, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to whether the Actonel reached the Plaintiff as alleged without substantial change in its condition and therefore deny such allegations. P&G and sanofi-aventis deny any remaining allegations.

19. In answer to paragraph 19 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

20. In answer to paragraph 20 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

21. In answer to paragraph 21 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

22. In answer to paragraph 22 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

COUNT II
NEGLIGENCE – NEGLIGENT MANUFACTURE

23. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 14 above.

24. In answer to paragraph 24 of the Complaint, P&G and sanofi-aventis state that they had a duty to comply with all applicable law, which they did. By way of further answer, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge. P&G and sanofi-aventis deny any remaining allegations.

25. In answer to paragraph 25 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

26. In answer to paragraph 26 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. P&G and sanofi-aventis deny the remaining allegations contained therein.

27. In answer to paragraph 27 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

28. In answer to paragraph 28 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

COUNT III
NEGLIGENCE – FAILURE TO WARN

29. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 14 above.

30. In answer to paragraph 30 of the Complaint, P&G and sanofi-aventis state that they had a duty to comply with all applicable law, which they did. By way of further answer, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge. P&G and sanofi-aventis deny any remaining allegations.

31. In answer to paragraph 31 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

32. In answer to paragraph 32 of the Complaint, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge. P&G and sanofi-aventis deny any remaining allegations.

33. In answer to paragraph 33 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

34. In answer to paragraph 34 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

35. In answer to paragraph 35 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

COUNT IV
BREACH OF EXPRESS WARRANTY

36. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 14 above.

37. In answer to paragraph 37 of the Complaint, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge. P&G and sanofi-aventis deny any remaining allegations.

38. In answer to paragraph 38 of the Complaint, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of the alleged reliance of Plaintiff and her health care providers on the alleged actions of P&G and sanofi-aventis and therefore deny such allegations. Furthermore, insofar as the allegations thereof suggest, imply or state that there are health risks, safety concerns and/or adverse reactions associated with Actonel, they are expressly denied. P&G and sanofi-aventis deny any remaining allegations.

39. In answer to paragraph 39 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

COUNT V
BREACH OF IMPLIED WARRANTY

40. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 14 above.

41. In answer to paragraph 41 of the Complaint, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief as to the truth or falsity of Plaintiff's alleged reliance on the alleged actions of P&G and sanofi-aventis and therefore deny such allegations. Furthermore, insofar as the allegations thereof suggest, imply or state that there are health risks, safety concerns and/or adverse reactions associated with Actonel, they are expressly denied. P&G and sanofi-aventis deny any remaining allegations.

42. In answer to paragraph 42 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

43. In answer to paragraph 43 of the Complaint, P&G and sanofi-aventis deny the allegations contained therein.

PRAYER FOR RELIEF

44. Plaintiff's Prayer for Relief paragraph of the Complaint, which begins with the word "WHEREFORE," does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, P&G and sanofi-aventis deny each and every allegation and assertion listed under the Prayer for Relief paragraph beginning with the word "WHEREFORE," including all sub-parts, and deny that Plaintiff is entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

45. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable P&G and sanofi-aventis to determine all of their legal, contractual and equitable rights, P&G and sanofi-aventis hereby give notice that they intend to rely upon such other defenses as may become available or appear during discovery proceedings

in this case and hereby reserve the right to amend and/or supplement this answer to assert any such defense at a future time and in conformity with the Federal Rules of Civil Procedure.

FIRST AFFIRMATIVE DEFENSE

46. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

47. Any product for which P&G and sanofi-aventis were responsible at the time of the occurrences or injuries alleged by Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and it was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product at issue in this case were legally adequate warnings and instructions.

THIRD AFFIRMATIVE DEFENSE

48. Plaintiff's claims are barred in whole or in part because P&G and sanofi-aventis provided adequate "direction or warnings" as to the use of any of its products within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

FOURTH AFFIRMATIVE DEFENSE

49. P&G and sanofi-aventis assert the applicability of comment k of the Restatement (Second) of Torts § 402A, which bars Plaintiff's claims in this lawsuit.

FIFTH AFFIRMATIVE DEFENSE

50. P&G and sanofi-aventis deny that Plaintiff used any product manufactured or marketed by P&G and sanofi-aventis as alleged in Plaintiff's Complaint.

SIXTH AFFIRMATIVE DEFENSE

51. Any and all damages alleged by Plaintiff may have been caused by misuse of the product at issue, failure to use the product properly, and/or alteration or negligent use of the product.

SEVENTH AFFIRMATIVE DEFENSE

52. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

53. The occurrences and injuries alleged by Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of third parties over whom P&G and sanofi-aventis had no control and for whom P&G and sanofi-aventis are not responsible.

NINTH AFFIRMATIVE DEFENSE

54. Plaintiff's claims may be barred by negligence and/or the contributory negligence of others, and/or by the assumption of risks, if any, inherent in the alleged use of the product at issue by Plaintiff and/or the treating physicians and/or other health care providers.

TENTH AFFIRMATIVE DEFENSE

55. If Plaintiff sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiff and/or of third parties, not from any negligence or breach of duty by P&G and sanofi-aventis.

ELEVENTH AFFIRMATIVE DEFENSE

56. The occurrences and injuries alleged by Plaintiff resulted from an intervening cause or a new and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrences and injuries alleged by Plaintiff.

Moreover, the occurrences and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any alleged breach of legal duty on the part of P&G and sanofi-aventis and the occurrences and injuries alleged by Plaintiff, and thereby become the immediate and/or sole cause and/or sole proximate cause of such occurrences and injuries, relieving P&G and sanofi-aventis of liability to Plaintiff or any other parties.

TWELFTH AFFIRMATIVE DEFENSE

57. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused, in whole or in part, by operation of nature or act of God.

THIRTEENTH AFFIRMATIVE DEFENSE

58. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of P&G and sanofi-aventis.

FOURTEENTH AFFIRMATIVE DEFENSE

59. If the Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses for which P&G and sanofi-aventis are not responsible.

FIFTEENTH AFFIRMATIVE DEFENSE

60. The Federal Food & Drug Administration ("FDA") has implemented a comprehensive regulatory scheme governing the safety and efficacy of prescription drugs. The drug at issue in this case (the "product" or "product at issue") was approved by the FDA pursuant to such applicable statutes and regulations and, pursuant to such, could only be used

pursuant to the prescription of a licensed prescriber. The labeling for the product at issue was also approved by the FDA and the marketing was conducted in conformity with the FDA's rules and regulations. Actonel was subject to and received pre-market approval by the Food & Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301. To the extent Plaintiff asserts claims based on P&G's and sanofi-aventis' adherence to and compliance with applicable federal laws, regulations and rule, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTEENTH AFFIRMATIVE DEFENSE

61. Plaintiff cannot recover because the product at issue was designed and/or made in accordance with the state of the art at the relevant time.

SEVENTEENTH AFFIRMATIVE DEFENSE

62. P&G and sanofi-aventis state that the benefits of the product at issue outweigh the risks, if any, which may be attendant to its use.

EIGHTEENTH AFFIRMATIVE DEFENSE

63. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations.

NINETEENTH AFFIRMATIVE DEFENSE

64. Plaintiff's claims are barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

TWENTIETH AFFIRMATIVE DEFENSE

65. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

TWENTY-FIRST AFFIRMATIVE DEFENSE

66. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

TWENTY-SECOND AFFIRMATIVE DEFENSE

67. Actonel is a prescription pharmaceutical that was available only upon the prescription of a licensed physician, and persons other than P&G and sanofi-aventis, including Plaintiff's treating physicians and health care personnel and institutions, stood in the position of learned intermediaries between P&G and sanofi-aventis and Plaintiff. Any claims against P&G and sanofi-aventis accordingly are barred in whole or in part by the learned intermediary doctrine because P&G's and sanofi-aventis' only obligation is to warn the Plaintiff's prescribing physician, and that obligation was fulfilled.

TWENTY-THIRD AFFIRMATIVE DEFENSE

68. Plaintiff's claims are barred as a matter of law pursuant to Restatement (Third) of Torts §§ 2,4, and 6.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

69. Plaintiff's claims relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

70. This case is more appropriately brought in a different venue.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

71. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, P&G's and sanofi-aventis' liability, if any, should be reduced accordingly.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

72. Plaintiff's claims are barred in whole or in part because Plaintiff has failed to mitigate the alleged damages.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

73. P&G and sanofi-aventis deny that they have been guilty of any conduct which warrants the issue of punitive damages being submitted to a jury.

TWENTY-NINTH AFFIRMATIVE DEFENSE

74. Any award of punitive damages to Plaintiff in this case would be in violation of the constitutional safeguards provided to Defendant under the Constitution of the United States of America.

THIRTIETH AFFIRMATIVE DEFENSE

75. With respect to Plaintiff's demand for punitive damages, P&G and sanofi-aventis specifically incorporate by reference any and all standards or limitations regarding the determination and/or enforceability of punitive damages awards which arose in the decisions of *BMW of North America v. Gore*, 116 U.S. 1589 (1996) (as extended by *Cooper Indus. v. Leatherman Tool Group*, 532 U.S. 424 (2001)) and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003)).

THIRTY-FIRST AFFIRMATIVE DEFENSE

76. Plaintiff is not entitled to recover exemplary or punitive damages because, to the extent that Plaintiff seeks punitive damages for an alleged act or omission of P&G and sanofi-

aventis, no act or omission was malicious, fraudulent, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

THIRTY-SECOND AFFIRMATIVE DEFENSE

77. Plaintiff is not entitled to punitive or exemplary damages because Actonel and its labeling were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

THIRTY-THIRD AFFIRMATIVE DEFENSE

78. The imposition of punitive or exemplary damages violates the Sixth Amendment of the United States Constitution because P&G and sanofi-aventis are not informed of the nature and cause of the accusation against them; thus, the allegations are void for vagueness.

JURY DEMAND

P&G and sanofi-aventis hereby demand a trial by jury on all of Plaintiff's claims.

WHEREFORE, Defendants P&G and sanofi-aventis pray for judgment as follows:

1. That Plaintiff take nothing by her Complaint;

2. For such other and further relief as the court may deem just and proper.

Dated: November 27, 2007

Respectfully submitted,

By: _____

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